

BEST AVAILABLE COPY

EXHIBIT 2

THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MEDRAD, INC.

Plaintiff,

v.

TYCO HEALTHCARE GROUP LP,
MALLINCKRODT INC.,
LIEBEL-FLARSHEIM CO., and
NEMOTO KYORINDO CO., LTD.,

Defendants.

Civil Action No. 01-1997

Judge Gary L. Lancaster

JURY TRIAL DEMANDED

MEDRAD, INC.'S PRETRIAL STATEMENT

Pursuant to Judge Lancaster's Case Management Order and Local Rule 16.1.4.A.,

Medrad, Inc. ("Medrad") files its Pretrial Statement, which includes the following:

- I. Introduction
- II. Pretrial Narrative Statement of Facts (Portions containing confidential material have not been submitted for publicly accessible electronic filing, pending ruling on Medrad's Motion for Leave to File Its Pretrial Statement under Seal)
- III. Statement of All Damages Claimed By Medrad
- IV. Witness List
- V. Deposition Designation
- VI. Exhibit List
- VII. Legal Issues to Be Addressed at Final Pretrial Conference
- VIII. List of Expert Reports (Portions containing confidential material have not been submitted for publicly accessible electronic filing, pending ruling on Medrad's Motion for Leave to File Its Pretrial Statement under Seal)

CONTAINS ATTORNEYS' EYES ONLY MATERIAL
SUBJECT TO PROTECTIVE ORDER

I. Introduction

Medrad contends that Defendants Tyco Healthcare Group LP, Mallinckrodt, Inc., Liebel-Flarsheim Co., (collectively "Tyco") and Nemoto Kyorindo Co., Ltd. ("Nemoto") have infringed and continue to infringe claims 9, 25-28, 30, and 33-38 of U.S. Patent No. RE37,602 ("the '602 patent") pursuant to 35 U.S.C. § 271 by making, selling and offering to sell in the United States and importing into the United States the Optistar MR and LE Contrast Delivery Systems ("Optistar injectors"). Medrad seeks compensatory damages as well as treble damages pursuant to 35 U.S.C. § 284 and attorney's fees pursuant to § 285. Moreover, Medrad requests that Tyco and Nemoto be permanently enjoined, pursuant to 35 U.S.C. § 283, from continuing to make and sell its infringing products.

Tyco and Nemoto deny that they infringe Medrad's '602 patent by making and selling their Optistar injectors and have asserted several affirmative defenses, including patent invalidity, patent unenforceability, improper grounds for requesting the reissue of a patent, and the doctrine of intervening rights. The defendants also counterclaimed alleging monopolization and attempted monopolization of the market for medical injectors for use with MRI under 15 U.S.C. § 2 and declaratory judgment of invalidity, unenforceability, intervening rights and non-infringement. On January 18, 2005, the Court granted Medrad's motion to bifurcate and stay defendants' Sherman Act counterclaim pending the resolution of the remaining issues in the case.

II. Pretrial Narrative Statement of Facts

(Portions of the Pretrial Narrative Statement of Facts containing confidential material have not been submitted for publicly accessible electronic filing, pending ruling on Medrad's Motion for Leave to File Its Pretrial Statement under Seal.)

A. Background

Medrad, headquartered in Indianola, Pennsylvania, is a worldwide leading provider of medical devices and services that enable and enhance imaging procedures for medical diagnosis and treatment. Medrad has a long history of innovation, beginning with founder Dr. M. Stephen Heilman's invention of the first angiographic injector in 1966. In 2003, the United States recognized Medrad by awarding it the Malcolm Baldrige National Quality Award in the manufacturing category, the top honor a U.S. company can achieve for business excellence.

1. The Patent-In-Suit

Medrad was the first to develop a successful injection system for use in conjunction with magnetic resonance ("MR") procedures to inject a contrast agent during imaging procedures, which can dramatically improve the quality of the diagnostic images produced by MR scanners. Medrad's pioneering invention of MR injection systems is disclosed in the patent-in-suit, the '602 patent, entitled "Patient Infusion System For Use With MRI" (assigned to Medrad). The '602 patent discloses an injection system that can successfully operate during MR procedures without interfering with the scanner's imaging process, thereby enhancing the medical usefulness of MR images.

The '602 patent is a "reissue" patent that had two predecessor patents. The first, U.S. Patent 5,494,036 ("the '036 patent"), was issued on February 27, 1996. Medrad then filed a

reissue application that resulted in U.S. Patent RE36,648 ("the '648 patent"), issued on April 11, 2000. Medrad filed another reissue application that resulted in the '602 patent, which issued on March 26, 2002. During the two reissue proceedings, the prior art on which defendants principally rely for their invalidity arguments was considered by the US Patent Office, and the PTO examiner concluded that the '602 patent was allowable over that prior art.

The following prior art was before the US Patent Office by Medrad during the prosecution of the '602 patent:

- Saini, Sanjay et al., "Technical Report: In Vitro Evaluation of a Mechanical Injector for Infusion of Magnetic Resonance Contrast Media," Investigative Radiology, vol. 26/No. 8, pp. 748-51 (Aug. 1991) ("the Saini article"),
- "Magnetic Resonance Injector Operation Manual," Medrad, Inc. (Nov. 17, 1987) ("the 1987 Manual"),
- GE Medical Systems Technical Publication entitled "Signa Site Planning," Direction 15002, Revision 14 (dated 1990) ("Signa Site Planning"),
- Ross, Ronald J. et al., "Site Location and Requirements for the Installation of a Nuclear Magnetic Resonance Scanning Unit," Magnetic Resonance Imaging: vol. 1, No. 1, pp. 29-33 (accepted Feb., 1982) (*Site Location and Requirements*),
- U.S. Patent No. 4,885,538 (the '538 patent),
- Mardiguian, Michel, "Controlling Radiated Emissions by Design," Chapman & Hall, 115 Fifth Avenue, New York, New York, pp. 237-255 (1992),
- Japanese Patent Publication 61-155846,
- Japanese Patent Publication 1-165010,
- Medex publication entitled, "AS200 Injector," facsimile transmission date of Jan. 25, 1989 ("the Medex brochure"),
- U.S. Patent No. 4,613,328 ("the '328 patent"),
- Nadel, Scott N. et al., "Detection of Acute Avascular Necrosis of the Femoral Head in Dogs: Dynamic Contrast-Enhanced MR Imaging vs. Spin-Echo and Stir Sequences," AJR: 159, pp. 1255-1261 (Dec. 1992),
- "Market Scan," Diagnostic Imaging, p. 61 (Sept. 1988),

- Karlik, S. J. et al., "*Patent Anesthesia and Monitoring at a 1.5-T MRI Installation*," *Magnetic Resonance in Medicine* 7, pp. 210-221 (1988) (Exhibit 10 to Tyco's Memo

2. Development of the Invention

Medrad's invention of an MR injector took many years of work and experimentation, and evolved over several experimental prototypes. Designing an injector that could operate in the MR environment, which requires that the injector be able to operate within a strong magnetic field, but at the same time not interfere with the highly sensitive MR scanner, proved a difficult challenge. In an effort to design such an injector, Medrad designed and built custom made engineering prototype injectors, referred to as the EM-1 prototype injectors, to be used experimentally to identify the performance requirements and the necessary technical design elements for a power injector in the MR environment. The EM-1 could not overcome technical problems in its design and was followed by the EM-2 prototype, a fundamentally different design.

The EM-1 prototype injectors were modified versions of Medrad's Mark V CT injection system. However, the requirements for performing in the MR environment were much different from the CT imaging modality, and so the system architecture of the Mark V injector was changed significantly for the EM-1 prototypes.

a. Configuration of the EM-1 Prototype Injectors

The EM-1 injector consisted of four components: (1) the remote panel controller located in the control room, (2) the CRC or "main unit," (3) the motor box and (4) the injector head. The main unit, which was located in the computer room (external to the shielded room) contained the control circuitry that controlled the injections in the EM-1 prototypes. Significantly, the main

unit supplied electric power over a cable to drive the motor in the motor box (which was located inside the shielded room). The main unit determined when to provide electric drive power over the cable to power the motor, when to shut off the electric power, and how much electric power to provide to drive the motor. No control information was transmitted from the main unit to either the motor box or injector head located inside the shielded room.

The motor box, which along with the powerhead was located inside the shielded room, of the EM-1 prototypes housed a motor and drive assembly for driving the syringe located on the injector head. The motor box, which included a PC card and potentiometer that were designed to ensure that the flexible drive shaft between the motor box and injector head was properly aligned, did not contain any control circuitry for controlling the injection of the EM-1 prototypes.

The final component of the EM-1 prototype injectors, the injector head, allowed a single syringe to be engaged with the drive mechanism of the EM-1 prototype injectors.

b. Testing of the EM-1 Prototype Injectors

Medrad tested the EM-1 prototype injectors to help develop an injector design that could operate in the MR environment, and to determine what configuration of an MR injector would precisely and reliably deliver contrast solution to create clearer MR images. To achieve these objectives, Medrad tested its EM-1 prototype injectors under conditions of actual clinical use at several different testing locations. The testing proved challenging and five years elapsed before Medrad solved the complex problems of designing an effective MR injector, due to the difficult noise suppression and noise immunity issues of using an MR injector in an MR environment. Notably, the operation of the EM-1 prototypes significantly influenced the magnetic field of the imaging system with which they were used – a result that was unacceptable in the determined eyes of Medrad.

Medrad maintained an appropriate level of confidentiality for the use of the EM-1

prototype injectors consistent with the need to test the prototypes in the setting of an MRI suite.

Medrad closely monitored the testing of the EM-1 prototypes and ensured that the injectors were being used in ways that would allow Medrad to obtain the requisite data to design its next generation prototype.

As a result of this monitoring, Medrad accumulated a significant amount of feedback regarding the EM-1 prototype injectors. This feedback allowed Medrad to make critical design alterations that eventually led Medrad to the development of the next generation prototype injector, known as the EM-2 injector, which was a very different device from and had a different system architecture than the EM-1.

c. Medrad's Next Generation Prototype Injector – The EM-2

Medrad developed the next generation of prototype injector – the EM-2 – to test a fundamentally different system architecture in an attempt to resolve the persistent noise problems encountered with the use of the EM-1 prototypes. The features claimed in Medrad's '602 patent were developed in connection with the work on the groundbreaking EM-2 prototype. One significant design alteration in the EM-2 was distributing the control functionality between a component outside the shielded room and a component inside the shielded room, (as opposed to having the control circuitry residing in the main unit outside the shielded room as in the EM-1 prototypes).

In the EM-2 Medrad also changed the nature of the link between the injector's components, so that the link carried control signals from outside the shielded room to inside the shielded room (the EM-1 prototypes instead transmitted electric drive power from outside to inside the room). The control link was substantially non-reactive with the MR scanner, so that

no interference was created and the MR images were not degraded. In addition, the EM-2 incorporated an injector head that could accommodate two syringes that were each engaged with a drive mechanism of the injector.

d. Medrad's Pre-Filled MR Cartridge Agreement With Squibb Diagnostics

On November 18, 1992, Medrad and Squibb Diagnostics ("Squibb") entered into a "Pre-Filled MR Cartridge Agreement" ("Pre-Filled Cartridge Agreement"). Under the terms of the Pre-Filled Cartridge Agreement, Medrad granted Squibb the rights to distribute pre-filled MR cartridges across the world.

As part of the Pre-Filled Cartridge Agreement, Medrad agreed to develop an MR injector that met the specifications of Schedules B or C of the Agreement. At the time of the Agreement, the design specifications for that injector had yet to be developed by Medrad, and Exhibits B and C were intentionally left blank. Medrad and Squibb did not agree on the design specifications for the injector to be sold under the Agreement until December, 1993.

The Pre-Filled Cartridge Agreement was not a sale or an offer for sale of the invention because the parties did not agree to the design specifications of the injector to be sold until after Medrad had filed the application that led to the '602 patent. Moreover, at that time Medrad was proceeding with general different design configurations, including an as-yet undeveloped Pilot Squibb injector. Further, the PTO examiner considered the facts regarding the Pre-Filled Cartridge Agreement and found the '602 patent allowable.

e. Medrad's Commercial MR Injectors

Medrad's first commercial MR injector was introduced in 1996 as the Spectris injection system, and was later succeeded by Medrad's current version, the Spectris Solaris injection system. Medrad's Spectris and Spectris Solaris ® injection systems have experienced

widespread commercial success. Medrad's U.S. sales of its MR power injectors have increased tenfold since its introduction in 1996. The annual growth in Medrad's sales during this period has averaged 45 percent.

Until the introduction of Tyco's infringing Optistar injector in 2000, Medrad's Spectris was the only commercially sold injector that was approved by the FDA for use in MR imaging procedures. To this day, only Medrad's Spectris and the infringing Optistar have been approved by the FDA.

3. Proceedings Before the US Patent Office Involving the Patent-In-Suit

a. Prosecution of U.S. Patent No. 5,494,036

The prosecution of the '036 patent began on November 26, 1993, when Arthur E. Uber, III, Seid Waddell, John Stulen and Jon E. Manley filed U.S. Patent Application No. 08/158,055 (hereinafter "the '055 application") entitled "Magnetic Resonance Imaging System." The '055 application initially included eleven claims, six of which were independent claims.

The '055 application issued as the '036 patent on February 27, 1996 to Messrs. Uber, Waddell, Stulen and Manley with twenty-three claims. On February 25, 1997, the PTO issued a Certificate of Correction for the '036 patent listing additional prior art references that were omitted from the face of the '036 patent.

b. Prosecution of U.S. Reissue Patent No. 36,648

On February 23, 1998, Medrad filed an application for reissue of the '036 patent. During the reissue proceeding, certain claims of the '036 patent were amended, others cancelled, and new claims added, Messrs. Dedola and Newell were added as inventors, and prior art references

that had come to the attention of Medrad were submitted to the Patent Office in Information Disclosure Statements.

The reissue application was assigned to a special group in the PTO, known as the "Patent Reengineering Lab," which was created to experiment with a more interactive examination process in an effort to streamline the process. As a result, the examination of the reissue application was "streamlined" and more informal. Rather than issue office actions that required a formal response, the PTO Examiner (the same examiner that handled the prosecution of the original application) frequently provided the applicants and the prosecuting attorney with informal "proposals" and tentative actions, and gave them the opportunity to respond informally and by amendment to convince the Examiner not to make the action formal, in writing. In addition, the Examiner and Applicants communicated these informal "proposals" by phone or facsimile, and in person. On April 11, 2000, the reissue application issued as the '648 patent to Messrs. Uber, Waddell, Manley, Stulen, Newell, and Dedola.

Subsequent to the issue of the '648 patent, Medrad filed a complaint in the United States International Trade Commission ("ITC") on April 25, 2000 against Tyco seeking a finding of infringement of the '648 patent under 19 U.S.C. § 337 (*In the Matter of: Certain Magnetic Resonance Injection Systems and Components Thereof*, Investigation No. 337-TA-434). At the conclusion of the ITC investigation, it was determined that the '648 patent technically failed to comply with 37 C.F.R. §1.175 (b)(1) because Medrad inadvertently failed to file a supplemental oath or declaration with the PTO before the allowance of the claims in the reissue patent. The Administrative Law Judge made a determination that the '648 patent was invalid for purposes of the ITC investigation.

c. Prosecution of U.S. Reissue Patent No. 37,602

As a result of the outcome of the ITC investigation, on November 16, 2000, Medrad filed a second reissue application to cure the technical oversight. The filing included, among other things, Reissue Declarations signed by each of the inventors noting the reason for the filing of the reissue application.

On June 8, 2001, Applicants filed an Information Disclosure Statement listing twenty-four U.S. patents, seven foreign patents, and fifty eight other publications. In addition, the Applicants detailed certain activities by Medrad, the assignee, to be considered pursuant to the provisions of the on-sale bar of 35 U.S.C. § 102(b). On March 26, 2002, the second reissue application issued as the '602 patent to Messrs. Uber, Waddell, Manley, Stulen, Newell, and Dedola.

In the reissue application that resulted in the '602 patent, the inventors stated that they believed that the '648 patent was partly inoperative on two grounds. First, they believed that the '648 patent was "partly inoperative for lack of a supplemental reissue declaration directed toward the overclaiming error in [claims 9 and 13 of the '036 patent]." The inventors believed that the "all errors" language in the original reissue declaration covered the overclaiming error, and that their omission of a supplemental reissue declaration occurred "without any deceptive intention on [their] part."

Second, the inventors stated that they believed the '648 patent to be "partly inoperative for lack of a supplemental reissue declaration by all of the inventors, in view of the initial determination" of invalidity by Administrative Law Judge Luckern. As part of the '602 reissue application, the inventors stated that they previously believed that their prior declarations were sufficient, and such error occurred "without any deceptive intention on [their] part." Medrad

fully complied with the applicable reissue procedures and 35 U.S.C. § 251¹ during the prosecution of the '602 patent, and the patent is valid and enforceable.

4. The History of Defendants' Infringing Optistar Injector

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¹ Medrad believes that defendants' contention that the '602 patent was not properly granted under the applicable reissue procedure is an issue to be determined by the Court and not the jury.

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D. The Defendants' Affirmative Defenses

Apart from alleging that the Optistar does not infringe the claims of the '602 patent, Tyco has alleged other defenses, including invalidity (lack of novelty, obviousness, failure to disclose the best mode), unenforceability (inequitable conduct), and procedural error in seeking the '602 reissue patent. For all of these defenses, the '602 patent is first presumed valid, and Tyco bears the burden of proof of its claims by clear and convincing evidence. Moreover, the fact that the '602 patent has been reviewed multiple times by the Patent Office enhances the presumption of validity.

a. Invalidity

With respect to invalidity, the defendants have argued that over 80 pieces of prior art collected by them either disclose the invention in the '602 patent or make the invention obvious. The principal items of prior art cited by the defendants were previously considered by the Patent Office, which found the '602 patent allowable over them. None of the references asserted by the defendants invalidate the '602 patent.

i. Prior Public Use

As discussed in detail above, the EM-1 prototype injectors were used by Medrad experimentally to determine the performance requirements of an injector for use in the MR environment. Since they were only used for experimental purposes, the EM-1 prototype injectors qualify under the "experimental use exception," and are therefore not prior art.

Moreover, also discussed above, the EM-1 prototype injectors were fundamentally different from the invention of the '602 patent. Specifically, the EM-1 prototypes did not have

(1) an *infusion apparatus control means* inside the shielded room, (2) a *communication control link* that was adapted to be substantially non-reactive with the magnetic field of the imaging system, and (3) an injector adapted to accommodate two syringes each operably engaged with a drive mechanism of the injector.

ii. On-Sale Bar

The defendants allege that the '602 patent is invalid because the invention of the '602 patent was "on-sale" shortly before the critical date³ of the patent as a result of an agreement between Medrad and Squibb Diagnostics relating to pre-filled syringe cartridges. As discussed above, the agreement omitted the section that was supposed to describe an injector to be developed and sold by Medrad because the parties had not discussed the features and specifications of the injector subject to the agreement— and, indeed, it was not for another year, well after the critical date, the specifications of the injector were discussed. There was no "meeting of the minds" prior to the critical date regarding the injector to be developed, and therefore no sale or offer for sale took place.

iii. Prior Publications

The defendants also claim that the '602 patent is invalid because certain prior art publications disclose the invention of the '602 patent or a combination of the publications make the invention obvious. The defendants' contentions are fundamentally flawed for several reasons.

First, the PTO has already considered the majority of these documents during prosecution of the '602 patent, and allowed the claims over these references. Furthermore, several of the documents, including the Medex AS200 brochure and Medrad's 1987 Magnetic Resonance

³ The critical date is November 26, 1992.

Injector Operation Manual, fail to qualify as prior art publications because they were not available to the relevant public. Moreover, none of the documents identified by Tyco, including the 1987 Manual, Medex brochure, and the Saini article, fully disclose the elements of the invention claimed in the '602 patent, nor does any combination of the documents make the invention obvious.

Specifically, the defendants point to a long list of documents that identify the need and desire to follow an injection of contrast agent with a saline flush. Although these documents do indeed recognize the long-felt and unresolved need for an injector that included such a feature, none of them disclose an injector that includes the elements of the invention claimed in the '602 patent.

The defendants also allege that the use of RF shielding to avoid interference with the magnetic field of the imaging system would have been obvious to a person of ordinary skill in the art. To date, however, the defendants have identified no successful MR injector that used shielded cables and a filter to create a substantially non-reactive communication control link passing from outside to inside the shielded scan room that did not also use a special communications protocol. Moreover, none of the references identified by Tyco disclose the use of shielded cables to form a substantially non-reactive communication control link for an MR injector.

b. Reissue Procedure

The defendants also contend that the '602 patent is invalid for failure to satisfy the statutory requirements of 35 U.S.C. § 251, arguing that there are procedural flaws in the patent because Medrad did not state a proper basis for seeking reissue under the statute. Medrad

submits that the defendants' allegation of procedural defects in the patent is contradicted by the case law, which unequivocally supports Medrad's position that the patent was properly issued.

c. **Best Mode**

The defendants incorrectly contend that the '602 patent is invalid because it fails to comply with the requirements of § 112, ¶ 1, which requires the inventor to disclose the best mode of practicing the invention. Medrad submits that the items discussed by the defendants were not the "best mode" of the invention, but were possible alternatives.

Medrad disclosed two alternative embodiments for the communicating control link in the '602 patent – infrared/optical communications transceivers, or a fiber optic communication link – both of which had advantages and disadvantages in the eyes of the inventors. In fact, Medrad's commercial MRI injector products have used both alternatives, infrared transceivers and fiber optics. The inventors had no subjective preference for optical transceivers over fiber optic cable in 1993, and optical transceivers were chosen initially for commercial reasons such as availability and cost. The defendants also point to the choice of materials for the injector and the choice of battery type as technical features supporting their best mode argument, but these were both routine details known in the field. The defendants' argument fails here as well.

d. **Inequitable Conduct**

The defendants have alleged that Medrad intentionally withheld material information regarding Medrad's prototype injector, copies of certain court papers or pleadings filed in this case's predecessor ITC proceeding, the English translation of brochures regarding certain Medex injectors, and certain facts regarding the agreement between Squibb and Medrad. Medrad did

not knowingly omit facts material to the prosecution of the '602 patent, and/or its predecessor patents, with the intent to mislead and/or deceive the Patent Examiner, as the defendants suggest.

During the prosecution of the '602 patent and its predecessor patents, Medrad fully complied with the requirement to submit material prior art of which it was aware, including all of the references to its prototype injectors and the agreement reached with Squibb. Further, Medrad did not have possession of some of the items about which the defendants complain. In particular, Medrad destroyed or returned the relevant court papers and pleadings from the ITC investigation pursuant to the agreement reached by counsel for all of the parties, including Tyco's counsel, in accordance with the Protective Order issued by the ITC. Moreover, Medrad never had any intent to withhold material items, rather, Medrad made voluminous disclosures of relevant materials to the Patent Office in an effort to fully comply with its obligations under the law.

III. Statement of All Damages Claimed By Medrad

Under 35 U.S.C. § 284, "[u]pon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer..." Thus, a patentee whose patent has been deemed valid and infringed, is entitled to either (1) an award of lost profits from sales the patentee would have made "but for" infringement, (2) a reasonable royalty on the infringing sales, or (3) a combination of (1) and (2).

A. Lost Profits Damages

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IV. Witness List

Medrad's list of witnesses pursuant to Local Rule 16.1.4.A.3 is attached as Exhibit 1.

V. Deposition Designation

Medrad's designations of testimony of those witnesses that Medrad expects to present by means of a deposition pursuant to Local Rule 16.1.4.A.4 is attached hereto as Exhibit 2.

Medrad has not included designations of deposition testimony for the sole purpose of showing admissibility of documents and things that were generated by Defendants and produced by them in the course of this litigation. Should Defendants object to the admissibility of documents that they generated and produced, Medrad will, in response, identify deposition testimony to establish admissibility of those exhibits, if necessary.

VI. Exhibit List

Medrad's list of exhibits pursuant to Local Rule 16.1.4.A.5 is attached as Exhibit 3.

Pursuant to an agreement between the parties, Medrad and the Defendants will exchange demonstrative exhibits on September 16, 2005, and Medrad will provide a list of its Demonstrative Exhibits at that time. Physical exhibits will be made available for inspection by opposing counsel at a mutually agreeable time.

In instances where a single page of a larger document is listed, Medrad intends to introduce the entire document as an exhibit.

VII. Legal Issues To Be Addressed at Final Pretrial Conference

Medrad's list of legal issues to be addressed at the final pretrial conference pursuant to Local Rule 16.1.4.A.6 is as follows:

1. *Allotment of Trial Time*: For each phase of trial, the allotment of time at trial for each party to present its case.
2. *Jury Instructions*: The timing of the reading of the preliminary and final jury instructions.
3. *Transitional and Interim Statements*: Whether a party will be allowed to introduce the testimony of a witness and presentation of depositions with a transitional statement and whether interim commentary to the jury will be permitted and the ground rules for such commentary.
4. *Technology in the Courtroom*: The use of technology in the courtroom, including but not limited to notebook computers, computer graphics, video monitors, overhead presentation technology such as "Elmo" equipment, etc.
5. *Witness and Exhibit Deadlines*: The deadline for exchanging lists of witnesses to be called at trial; the deadline for exchanging exhibits to be used the following day at trial.
6. *Evidence Provided to Jury During Deliberations*: Whether the jury will be able to take evidence and demonstrative exhibits into the jury room during deliberations and the format in which it is to be provided, e.g., separate notebooks on a per witness basis or master notebook.
7. *Right to Supplement or Amend*: The parties rights to amend or supplement the Pretrial Statement, proposed jury instructions, proposed verdict form and/or special interrogatories to the extent required by, among other things, the Court's decisions on the pending motions or any other ruling by the Court.
8. *Motions in Limine*: Preclusion of Tyco from offering evidence as per Medrad's motions *in limine*.
9. *Summary Judgment Motions*: Resolution of pending summary judgment motions, if any.
10. Whether certain issues should be tried to the Judge or jury:
 - a. *Reissue Procedure – '602 Patent*: Whether the correctness of the reissue procedure of the '602 patent should be tried to the Judge or jury. Medrad believes that the determination of whether an error can be corrected by reissue is a question of law for the Judge to decide.

- b. *Intervening Rights*: Whether intervening rights should be tried to the Judge or jury. Medrad believes that the question of intervening rights is a question of law for the Judge to decide.
- c. *Inequitable Conduct*: Whether inequitable conduct should be tried to the Judge or jury. Medrad believes that inequitable conduct is an equitable issue for the Judge to decide.

11. *Separation of Issues for the Presentation of Evidence*: Medrad proposes to try the issues in the case in the following order:

Phase 1: Jury trial on infringement, validity, damages, and willfulness.

Phase 2 (to be held next business day after jury begins deliberations): Bench trial on inequitable conduct, intervening rights, and factual issues, if any, concerning defective reissue.

12. *Order of the Presentation of Proofs at Trial*: In the interest of judicial economy, Medrad proposes the following order of proofs for the first phase of trial:

- a. Opening statements
- b. Medrad witnesses
- c. Tyco witnesses
- d. Medrad rebuttal witnesses
- e. Closing statements

With respect to the second phase of trial (bench trial), Medrad proposes the following order of proofs:

- a. Opening statements
- b. Tyco witnesses
- c. Medrad witnesses
- d. Tyco rebuttal witnesses
- e. Closing statements

VIII. List of Expert Reports

Medrad's expert reports filed pursuant to Local Rule 16.1.4.A.7 are attached as Exhibit 4.

(Portions of expert reports containing confidential material have not been submitted for publicly accessible electronic filing, pending ruling on Medrad's Motion for Leave to File Its Pretrial Statement under Seal.)

Respectfully submitted,

Dated: August 9, 2005

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of August, 2005, I electronically filed the foregoing
MEDRAD, INC.'S PRETRIAL STATEMENT, with the Clerk of the Court using the
CM/ECF system which will send notification of filing to the following:

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Date: August 9, 2005

/s Robert J. Walters
Counsel for Medrad, Inc.

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